

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/646,268	MARCHIONNI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	SHARON WEN	1644	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 12/29/2008; 3/24/2009.
2. ☒ The allowed claim(s) is/are 1, 3-7, 9-15, 17-18.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
  - \* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

**Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |   |
|---|---|
| <ol style="list-style-type: none"> <li>1. <input type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br/>Paper No./Mail Date _____</li> <li>4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br/>of Biological Material</li> </ol> | <ol style="list-style-type: none"> <li>5. <input type="checkbox"/> Notice of Informal Patent Application</li> <li>6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br/>Paper No./Mail Date <u>03/24/2009</u> .</li> <li>7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment</li> <li>8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance</li> <li>9. <input type="checkbox"/> Other _____.</li> </ol> |
|---|---|

/Phillip Gambel/  
Primary Examiner, Art Unit 1644

/Sharon Wen/  
Examiner, Art Unit 1644

### DETAILED ACTION

1. Applicant's amendment, filed 12/29/2008, has been entered.  
Claims 17 and 18 have been added.  
Claims 2 and 16 have been canceled.  
Claims 1, 3-15, 17-18 are pending.  
Upon further consideration, the withdrawn claims 6-10 have been rejoined.

### EXAMINER'S AMENDMENT

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Sarah Fashena on 03/24/2008.

3. The claims have been amended as follows:

-- Claim 1. (currently amended) A method for treating congestive heart failure in a mammal, said method comprising administering a polypeptide comprising an epidermal growth factor-like (EGF-like) domain to said mammal, wherein said EGF-like domain is encoded by a neuregulin NRG-2 gene, wherein said polypeptide comprises the amino acid sequence of SEQ ID NO: 11 and said administering is in an amount effective to treat congestive heart failure in said mammal. --

-- Claim 6. (currently amended) The method of claim 4, wherein said cardiotoxic compound is an anthracycline; an alcohol; or cocaine. --

Claim 8. (canceled)

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-- Claim 11. (currently amended) The method of claim 1, wherein said polypeptide is administered ~~prior to or~~ after the diagnosis of congestive heart failure in said mammal. --

-- Claim 14. (currently amended) The method of claim 1, wherein said method ~~prevents~~ decreases progression of myocardial thinning. --

--Claim 18. (currently amended) A method for treating congestive heart failure in a mammal, said method comprising:

administering a polypeptide comprising an epidermal growth factor-like (EGF-like) domain to said mammal, wherein said epidermal growth factor-like (EGF-like) domain comprises ~~an~~ the EGF-like domain of SEQ ID NO: 11 and said administering is in an amount effective to treat congestive heart failure in said mammal. --

#### **Reasons for Allowance**

4. The following is an examiner's statement of reasons for allowance:

Applicant's amendment, filed 12/29/2008, has obviated the previous enablement rejection under 35 USC 112, first paragraph. The method for treating congestive heart failure comprising administering a polypeptide of SEQ ID NO: 11 encoded by a neuregulin 2 gene appear to be free of prior art.

5. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON WEN whose telephone number is (571)270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571)272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Wen/

Examiner, Art Unit 1644

March 25, 2009

/Phillip Gambel/

Primary Examiner

Technology Center 1600

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March 26, 2009